REMARKS

Claims 1-170 are pending in the application. Claims 1, 110, 131 and 154 are independent. Reconsideration of this application, in view of the following remarks, is respectfully requested.

Rejection Under 35 U.S.C. § 103

Claims 1-19, 22-26, 28-43, 46-66, 69-96, 98-116, 119-135, 137-138, 141-165 and 168-170 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gray, U.S. Patent No. 6,041,801 in view of Coffee et al., U.S. Patent No. 6,595,208, and further in view of Tisone et al., U.S. Patent No. 6,063,339. Claims 9-10, 19, 25, 26, 42, 43, 6-66, 69-74, 82-88, 115, 116, 137, 138 and 162-165 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gray in view of Coffee as applied to the claims above, and further in view of Sugahara, U.S. Patent No. 5,508,726. These rejections are respectfully traversed.

Applicants submit that the prior art of record fails to teach or suggest each and every limitation of the unique combination of limitations of the claimed invention. For example, with respect to claim 1, Applicants submit that the prior art of record fails to teach or suggest the unique combination of limitations of the claimed invention, including the feature(s) of: "a positive displacement pump for delivery of metered quantities of system liquid through the assembly to displace the barrier to deliver sample liquid through the nozzle bore."

With respect to claim 110, Applicants submit that the prior art of record fails to teach or suggest the unique combination of limitations of the claimed invention, including the feature(s)

of: "a positive displacement pump for delivery of metered quantities of system liquid through the assembly to cause the divider barrier to move into and out of the sample liquid reservoir."

With respect to claim 131, Applicants submit that the prior art of record fails to teach or suggest the unique combination of limitations of the claimed invention, including the feature(s) of: "a positive displacement pump for delivery of metered quantities of system liquid through the assembly to cause the divider barrier to move into and out of the sample liquid reservoir."

With respect to claim 154, Applicants submit that the prior art of record fails to teach or suggest the unique combination of limitations of the claimed invention, including the feature(s) of: "at least two positive displacement pumps connected in parallel, one pump having a working stroke displacing a volume at least about ten times more than the volume displaced by the other pump." Accordingly, these rejections should be withdrawn.

Gray et al. is directed to a system and method for measuring when fluid has stopped flowing within a line. In view of this, the Gray et al. device is quite different from the present invention. Referring to the Examiner's Office Action, the Examiner recognizes that Gray et al. fails to disclose a positive displacement pump as recited in independent claims 1, 110, 131 and 154. However, the Examiner relies on the Coffee et al. reference to modify Gray et al. to arrive at the presently claimed invention. Applicants respectfully submit that it would not have been obvious to one having ordinary skill in the art to modify the Gray et al. device in the manner suggested by the Examiner.

The Gray et al. device is concerned with ensuring that there is a constant flow of a substance such as dialysis fluid or blood through the assembly and into a patient that is

connected to the assembly. This substance is not housed within the assembly, but is attached or connected to the assembly, as a bag of blood, and the assembly then ensures that the blood is pumped through the assembly and into the patient continuously at the required rate until the supply of the substance (for example, in the blood bag) is depleted.

The Examiner is correct in his assertion that the apparatus of Gray et al. includes a membrane between the system and sample liquid. However, the membrane of Gray et al. is the same as the membrane in all diaphragm pumps, with the membrane simply operating as a pumping membrane. The objective of the apparatus disclosed in Gray et al. is to ensure that the flow of the substance through the apparatus and into the patient is constant and the assembly can, in turn, detect if the flow of the substance has stopped such as when one of the lines of the assembly becomes occluded. If this occurs, the assembly can then send out a relevant warning signal. The latter feature is the important aspect of Gray et al.

The objective of the present invention is completely different to that as disclosed in Gray et al. The membrane in the present invention ensures that there is no contamination between the sample liquid and the system liquid. Furthermore, and due to the incompressibility of the membrane, the assembly according to the present invention can dispense minute, metered quantities of the sample liquid when required. The present invention is not concerned with the constant flow of a liquid through the assembly and therefore there is no requirement for the assembly to be able to detect if the sample liquid has stopped flowing through it. The required quantity of sample liquid according to the present invention is only expelled from the assembly when the positive displacement pump is actuated manually or automatically as the case may be.

Therefore, if one was trying to overcome the problems associated with using a gas bubble in an assembly for dispelling metered, minute quantities of a sample liquid, as is the case with the present invention, it is unlikely that they would revert to the teachings of Gray et al., as Gray et al. is evidently directed toward overcoming a completely different problem.

In any event, referring to Figure 1 of Gray et al., a flexible membrane 12 is moved up and down within a chamber 11 in response to pressure changes in the second fluid (see column 3, lines 43-45). Referring to column 4, lines 24-32 of Gray et al., the membrane 12 is moved toward or away from the wall of the chamber 11 to pump the first fluid 13 therethrough. This movement of the membrane 12 is required to pump the fluid 13 through the chamber 11. Specifically, the membrane 12 is moved toward the tank reservoir 17 to bring fluid 13 into the chamber 11 through the inlet 23. The membrane is then moved away from the tank reservoir 17 to force the fluid 13 out of the outlet 22. If the Gray et al. device were modified to use a positive displacement pump, then the intended operability of the Gray et al. device would be destroyed. Therefore, such a modification would be non-obvious.

Specifically, if a positive displacement pump were used in Gray et al., then the membrane would not be movable back and forth as required to feed the fluid 13 into the chamber 11 from the inlet 23 and out of the chamber 11 through the outlet 22. Therefore, only the fluid that is in the chamber 11 at any particular time could be fed out of the outlet 22 by the positive displacement pump, additional fluid 13 in, for example, a blood bag could not be fed into the chamber 11. In view of this, one having ordinary skill in the art would not modify the Gray et al. device to include a positive displacement pump as disclosed by Coffee et al. Therefore,

independent claims 1, 110, 131 and 154 are non-obvious over the combination of Gray et al. and Coffee et al.

With regard to the teachings of Tisone et al. and Sugahara, neither of these references provides a sufficient teaching to use a positive displacement in the Gray et al. device. Therefore, these references fail to make up for the deficiencies of Gray et al. and Coffee et al.

With regard to the dependent claims, Applicants respectfully submit that these claims are allowable due to their respective dependence on the independent claims, as well as due to the additional recitations in these claims.

In view of the above remarks, Applicants respectfully submit that claims 1-19, 22-26, 28-43, 46-66, 69-96, 98-116, 119-138, 141-165 and 168-170 clearly define the present invention over the references relied on by the Examiner. Accordingly, reconsideration and withdrawal of the Examiner's rejections under 35 U.S.C. § 103 are respectfully requested.

Allowable Subject Matter

Claims 20, 21, 27, 44, 45, 67, 68, 97, 117, 118, 139, 140, 166 and 167 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants greatly appreciate the indication of the allowable subject matter by the Examiner. However, for the above reasons, it is believed that independent claims 1, 110, 131 and 154 define the present invention over the references relied on by the Examiner. Therefore, the objected to claims have not been rewritten independent form at this time.

CONCLUSION

Since the remaining references cited by the Examiner have not been utilized to reject the claims, but merely to show the state-of- the-art, no further comments are deemed necessary with respect thereto.

All the stated grounds of rejection have been properly traversed and/or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently pending rejections and that they be withdrawn.

It is believed that a full and complete response has been made to the Office Action, and that as such, the Examiner is respectfully requested to send the application to Issue.

In the event there are any matters remaining in this application, the Examiner is invited to contact Paul C. Lewis, Registration No. 43,368 at (703) 205-8000 in the Washington, D.C. area.

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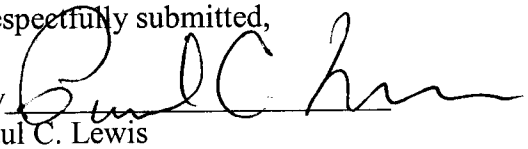
Respectfully submitted,

By 

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